REMARKS

Claim16 is presented in order to provide a generic linking claim under MPEP § 809.02. No new matter has been added.

The Examiner has withdrawn claims 13-15 from prosecution as requiring a burdensome search. As understood, there was a Restriction Requirement on September 4, 2001 in response to which Applicants cancelled all pending claims 1-6 and added new claims 7-15. Between the two enumerated groups of peptides and polypeptides, Applicants elected peptides.

The Office Action states "[i]n a second restriction, applicants also elected SEQ ID NO: 4." It is unclear where this requirement or election occurred; no such papers are within Applicants' filewrapper. If there was a second written restriction requirement to which Applicant elected SEQ ID NO: 4 without traverse, then claims 13-16 should be cancelled. However, it is believed that any imposition on searching should be minor and expedient. Moreover, the undersigned respectfully urges that any request should have been couched as a Selection of Species Requirement since it is thought that Restriction would be improper among the closely related proteins of SEQ ID NOS: 4, 11 and 21. Of course, in that latter event, new claim 16 is properly interposed since SEQ ID NO: 4 will be examined first, and the examination expanded in due course to encompass the remaining species as the selected species is allowable.

In any event, clarification is respectfully requested.

The specification has been objected to as being informal for containing a misdescriptive title, for not setting forth the file history, as not setting forth SEQ ID NO identifiers concerning Figures 1-7 and as not providing an Abstract of the disclosure.

These matters have all been attended to above in conformity with the Examiner's kind suggestions. Accordingly, these objections are all met.

Claims 7-12 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

By way of background the claimed subject matter is a secreted protein isolated from human stomach cancer[1/] that is sufficiently similar to mouse cornichon (PID Accession No. 2460430) that those of ordinary skill plainly expect and believe it to share activity with this morphogenesis-involved protein.[2/]

As noted, the claims are rejected under 35 U.S.C. § 101 as not having a specific and substantial utility that is credible (USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1098). In this regard, the Examiner necessarily contends (i) the activity of the present invention is not credible since (ii) those of ordinary skill recognize protein activity cannot be predicted from known homologous sequences. According to the Examiner, the pending claims do not satisfy the utility requirement of 35 USC 101 because, given the state of the art, structure-function analysis is unpredictable.[3/] This basis of rejection is, respectfully submitted, without foundation either in law or in fact.

1/ Specification page 48, line 4.

2/ See Roth et al., Cell Vol. 81 (1985) 967-8 for a discussion of such activity.

3/ Regarding the Examiner's technical analyses of the unpredictable activity resulting from amino acid changes, such is based on old art and is not the current position of either those of ordinary skill, or the Patent and Trademark Office. That is, while changes do occur (and some are drastic), similarity is, nevertheless, now reasonably expected, as discussed below.

The Examiner's point concerning the unpredictability of protein activity from known homologous sequences is not well-taken by those of ordinary skill. See, e.g., Principles of Protein Structure, Cantor, ed. (1978) 167 wherein it is explicitly taught that

> "[h]omologous proteins result from speciation or differentiation. Comparisons between homologous proteins have yielded general rules for protein structures (citing Schulz, Angew. Chem. Int. Edit., Vol. 16 (1977) 23-33). . . . In this context it is often useful to distinguish between protein speciation and protein differentiation (citing Molecular evolution and Polymorphism, Kimura ed. (1977) National Institute of Genetics, Mishima, Japan). Speciation is the evolution of homologous proteins possessing a common function in different organisms."

This knowledge is summarized in the art as evidencing that establishing homology between the unknown and reference proteins permits the skilled artisan to assume the unknown unexpressed protein and the known reference protein have the same function. Functional Genomics, Science, Vol. 278, No. 601 (1997).

This is not an aberrant position; similarly, the American Society of Human Genetics ("ASHG") similarly acknowledges "sequence homology is a useful predictor of gene function." Letter from Ronald Worton, Ph.D., President, ASHG, to the Honorable Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Unites States Patent and Trademark Office at 2 (Mar. 22, 2000) (on file with the USPTO).

Additionally, the USPTO too explicitly recognizes the state of this art in Example 10 of the Utility Training Materials: DNA fragments encoding a Full Open Reading Frame (ORF). In the example the Examiner is directed not to reject the claims merely because the applicant's asserted utility is premised on the "overall level of sequence

similarity between SEQ ID NO:3 [the unknown sequence] and the consensus sequence of the known DNA ligases that are presented in the specification." Indeed, Example 10 acknowledges that "homology between the known and unknown protein is sufficient to ascribe the known protein's function to the unknown; thus the claim possesses credible, substantial, and specific utility." Id. at 54 (emphasis added).

Although the guidelines make clear there is no minimum percentage required and directs the Examining corp not to focus on minimum homology criteria, Applicants note that guideline Example 10 is founded upon a 90% homology. The subject matter under examination surpasses this value with a 99.3% homology.[4/]

Moreover, the PTO acknowledges as well utility is well-established if it is readily apparent to one skilled in the art. Id. at 55. This is in conformity with the law promulgated by the Federal Circuit, which notes 35 U.S.C. 112 can be satisfied even by "genus claims to nucleic acids based on their hybridization properties, . . . [if the subject matter of the claims will] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." Enzo Biochem v. Gen-Probe, Appeal No. 01-1230 slip op. granting reh'g at 15 (Fed. Cir. July 15, 2002).

See for instance, in In re Folkers, 145 USPQ 390 (CCPA 1965), where a new compound belonging to the known family of quinones and hydroquinones was alleged, without more, to have the electron transport activity of that known class. Id at 393. The predecessor court to the Federal Circuit held that function is inferred based on

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[4/] Specification page 48, lines 23-24.

similarity to a substance with a known function. Id. Similarly, in In re Brana 34 USPQ 1436, 1442 (Fed. Cir. 1995), the Federal Circuit noted

> "[a]lthough it is true that minor changes in chemical compounds can radically alter their effects on the human body, evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility."

Applicants wish to point out that, at the very least, the resemblance of the present invention to specific proteins of known activity makes it clear the present invention can be further utilized as research tools for better characterizing the prior art mouse cornichon compound. Regarding this point, such asserted utility, e.g., to better characterize particular prior art compounds, is plainly specific. That is, while specific utility excludes generalized research tools like probes, such is not so, however, when the target being probed for is already known. Revised Interim Utility Guidelines Training Materials at 50-53.[5/]

Accordingly, respectfully submitted, the rejection under 35 U.S.C. § 101 is overcome and withdrawal thereof is earnestly solicited.

Claims 7-12 are also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However,

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[5/] In this regard, the PTO decided long ago that the ESTs must be rejected since use as research tools is not specific and they have insufficient homology to support a specific, substantial and credible utility. However, such logic (used in the context of ESTs) does not extend to full-length homology-based sequences if the homologous prior art sequence has a known function, since their use as research tools is plainly specific to the homologous prior art sequence. See the Federal Circuit Bar Journal, Vol. 11, No. 4 (2002) 918.

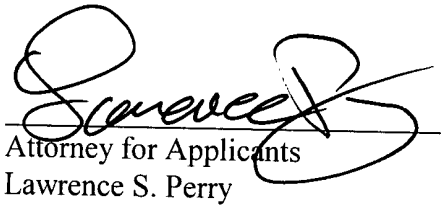
as seen explained above, the present invention is supported by a specific and substantial utility.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 7-16 remain presented for continued prosecution, with rejoinder of claims 13-16 being respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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The paragraphs from specification page 3, line 27 to page 4, line 15 have been amended as follows:

Fig. 1: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP01434 (SEQ ID NOS: 1, 8 and 15).

Fig. 2: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP01512 (SEQ ID NOS: 2, 9 and 17).

Fig. 3: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP02080 (SEQ ID NOS: 3, 10 and 19).

Fig. 4: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP02239 (SEQ ID NOS: 4, 11 and 21).

Fig. 5: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP02375 (SEQ ID NOS: 5, 12 and 23).

Fig. 6: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP10517 (SEQ ID NOS: 6, 13 and 25).

Fig. 7: A figure depicting the hydrophobicity/hydrophilicity profile of the protein encoded by clone HP10521 (SEQ ID NOS: 7, 14 and 27).